

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND)
COMPOUNDING PHARMACY, INC.) MDL No. 2419
PRODUCTS LIABILITY LITIGATION) Dkt. No. 1:13-md-2419-RWZ

This Document Relates to:)

Suits Identified in Exhibit A to the)
Tennessee Clinic Defendants' Motion for)
Summary Judgment [Dkt. 775-1])

)

**Response of Tennessee Clinic Defendants to the
Plaintiffs' Steering Committee's Motion for Leave to File Reply
in Support of the Plaintiffs' Steering Committee's Rule 56(d) Response
to the Tennessee Clinic Defendants' Motion for Summary Judgment**

Saint Thomas Outpatient Neurosurgical Center, LLC; Howell Allen Clinic, a Professional Corporation; John W. Culclasure, MD; Debra V. Schamberg, RN; Specialty Surgery Center, Crossville, PLLC; Kenneth R. Lister, MD; and Kenneth Lister, MD, PC (collectively "the Tennessee Clinic Defendants") respectfully request that the Court deny the Plaintiffs' Steering Committee's ("PSC") Motion for Leave to File Reply in Support of the Plaintiffs' Steering Committee's Rule 56(d) Response to the Tennessee Clinic Defendants' Motion for Summary Judgment [Dkt. 1061]. Additional briefing is unnecessary and falls outside the agreed-upon and Court-approved briefing schedule.¹

The PSC's "need" to respond to the withdrawal of two statements from the Defendants' original Statement of Undisputed Material Facts is an obvious pretext. The withdrawal of two statements of material fact should *lessen* the need for briefing on the Motion for Summary Judgment, not *add* to it. The PSC simply wants another "bite at the apple" to bolster its unpersuasive Rule 56(d) Response.

¹ The agreed-upon briefing schedule is at Dkt. 884.

Accordingly, the PSC's Motion should be denied and the Court should rule on the Tennessee Clinic Defendants' Motion for Summary Judgment on the extensive briefing already filed.

Background

At the December 13, 2013 status conference, Judge Saylor instructed the defendants to file dispositive motions that applied to a "substantial number of cases" by January 10, 2014.² On January 10, 2014, the Tennessee Clinic Defendants filed their Motion for Summary Judgment, moving for summary judgment in 33 cases that failed to comply with Tennessee's requirement that a certificate of good faith be filed in "health care liability actions."³ ⁴

Subsequently, the PSC proposed a briefing schedule, which the Tennessee Clinic Defendants agreed to with minor variation.⁵ The briefing schedule permits the typical motion-response-reply. It does *not* permit the PSC to file a sur-reply. On February 3, 2014, the parties submitted a joint motion for entry of their agreed briefing schedule.⁶

At the February 6, 2014 status conference, Judge Saylor discussed the briefing schedule with the parties but expressed no reservations about the Tennessee Clinic Defendants' decision to file the dispositive motion as a motion for summary judgment rather than a motion to dismiss.⁷ ⁸ On February 7, 2014, Judge Saylor granted the motion setting the parties' agreed briefing schedule.⁹

² Hrg Tr. 43:19-44:7 (Dec. 12, 2013 status conference).

³ Dkt. 774.

⁴ TENN. CODE ANN. § 29-26-122.

⁵ Dkt. 884.

⁶ Dkt. 845.

⁷ Hrg Tr. 35:2-37:11 (Feb. 6, 2014 status conference).

On February 24, 2014, the PSC filed its Fed. R. Civ. P. 56(d) Response to the Tennessee Clinic Defendants' Motion for Summary Judgment.¹⁰ ¹¹ In it, the PSC argued that the Court should defer deciding the Defendants' Motion for Summary Judgment and allow discovery on certain issues.¹²

On March 14, 2014, the Tennessee Clinic Defendants filed their Reply to the PSC's Response to the Defendants' Motion for Summary Judgment.¹³ ¹⁴ With their Reply, the Defendants contemporaneously withdrew two statements from their original Statement of Undisputed Material Facts by filing an Amended Statement of Undisputed Material Facts.¹⁵

On March 27, 2014, the PSC asked counsel for the Tennessee Clinic Defendants to consent to the PSC filing a sur-reply to the Tennessee Clinic Defendants' Reply to the PSC's Rule 56(d) Response.¹⁶ ¹⁷ Receiving no reasonable explanation from the

⁸ The Tennessee Clinic Defendants explicitly acknowledge in their Motion for Summary Judgment that it could likely be decided as a Motion to Dismiss. Dkt. 775, fn. 1. The supporting affidavits filed with the Motion for Summary Judgment conclusively establish that the Plaintiffs' injuries were related to the provision of health care services, which the Plaintiffs have not (yet) disputed. Dkts. 777, 778.

⁹ Dkt. 884.

¹⁰ Dkt. 948.

¹¹ The parties agreed to, and the Court ordered, a modification to the briefing schedule to grant the PSC additional time to file its response. Dkts. 941, 1101.

¹² Dkt. 948, p. 1.

¹³ Dkt. 1015.

¹⁴ The deadline for the Defendants' reply was negotiated by the parties but was inadvertently left off the proposed briefing schedule submitted to the Court. The Court granted the parties' motion to amend the briefing schedule to add the reply deadline. Dkts. 962, 963.

¹⁵ Dkts. 1016, 1017.

¹⁶ The email exchange between the PSC and counsel for the Tennessee Clinic Defendants demonstrating the lack of substantive explanation from the PSC is attached as Exhibit A.

¹⁷ The PSC terms their proposed pleading a "Reply." But, it is obviously a sur-reply. The Defendants filed their Motion for Summary Judgment. The PSC filed their Response, arguing that additional discovery is necessary before ruling on the motion. The Defendants filed their Reply, asserting that the Court can rule on the motion as briefed without discovery. The PSC now requests leave to file a sur-reply to the Defendants' Reply.

PSC for why additional briefing was necessary, the Defendants respectfully declined to agree to the request.¹⁸

Law and Argument

The parties agreed to a briefing schedule on the Tennessee Clinic Defendants' Motion for Summary Judgment to proceed in the usual fashion – the Defendants would file their motion; the PSC would file its Rule 56(d) response; and the Defendants would file a reply.¹⁹ Judge Saylor approved the briefing schedule after some discussion at the December 12, 2013, status conference, fully aware of the substance of the briefing schedule.²⁰ The parties have completed the briefing allotted by the Court. The Motion for Summary Judgment is ripe for decision. The PSC's Motion for Leave to File a "Reply" simply seeks to have the last word on the issues covered by the Motion for Summary Judgment. The Court should deny the PSC's Motion and rule on the Motion for Summary Judgment.

First, and importantly, the Tennessee Clinic Defendants note that the filing before the Court is the PSC's three-paragraph Motion for Leave to File a Reply, not the twelve-page proposed sur-reply attached to the Motion as an exhibit.²¹ The Court need not consider the substance of the sur-reply in ruling on the instant Motion. The only question before the Court is whether the PSC has demonstrated adequate reason to justify leave to file additional briefing on the pending Motion for Summary Judgment at Dkt. 774.

¹⁸ Exhibit A.

¹⁹ Dkt. 845.

²⁰ Hrg Tr. 43:19-44:7 (Dec. 12, 2013 status conference).

²¹ Dkt. 1061.

The PSC's Motion fails to explain *why* additional briefing is necessary to address the *withdrawal* of two statements from the Tennessee Clinic Defendants' Statement of Undisputed Material Facts.

Instead, the PSC presumptuously attached its proposed sur-reply, which necessitates the Court review the pleading before deciding whether to even allow it.²² The PSC simply wants to bolster its Rule 56(d) Response. In their Motion, the PSC even acknowledges that the purpose of the additional briefing is to "allow the PSC to address arguments made in the Tennessee Defendants' Response."²³

In the Motion, the PSC spends a sum total of three sentences explaining (or, more accurately, failing to explain) *why* a sur-reply is necessary to address the *removal* of two statements from the Statement of Undisputed Material Facts. The Defendants concede that the statements withdrawn from the Defendants' Statement of Undisputed Material Facts²⁴ are immaterial to resolution of the Motion for Summary Judgment.²⁵ Importantly, neither fact was relied upon in the Motion for Summary Judgment or Memorandum in Support.^{26 27} The withdrawal of these two statements should narrow the issues before the Court, not require any briefing.

²² Filing the proposed additional briefing as an exhibit to the Motion for Leave, necessitating the Court review it before even granting leave to file it, negates the leave requirement. The PSC has done this before. *E.g.*, Dkt. 987-1.

²³ Dkt. 1061, p. 2.

²⁴ The two withdrawn facts are:

¶ 6: During epidural steroid injections, Dr. Culclasure followed a procedure that complied with the recognized standard of acceptable professional practice.

¶ 7: During epidural steroid injections, Dr. Lister followed a procedure that complied with the recognized standard of acceptable professional practice.

²⁵ Candidly, they should not have been included with the Defendants' original Statement of Undisputed Material Facts.

²⁶ Oddly, given the PSC's focus on the need for discovery on this issue, the PSC does not allege a violation of the standard of care with respect to the actual epidural steroid injection procedure in the Master Complaint or individual complaints. Arguing that discovery is necessary on this point to resolve the Motion for Summary Judgment is clearly a red herring. Regardless, the Motion for Summary Judgment does not seek summary judgment on whether Drs. Culclasure and Lister complied with the standard of

Whether Dr. Culclasure and Dr. Lister violated the standard of care in performing the Plaintiffs' epidural steroid injection procedures has no bearing on whether the Plaintiffs were required to file a certificate of good faith with their original complaints as required by Tenn. Code Ann. § 29-26-122. The Defendants have withdrawn them from the original Statement of Undisputed Material Facts. Whether the Court chooses to construe the statements as withdrawn pursuant to the Amended Statement of Material Facts or simply conceded, no amount of additional briefing by the PSC will make these statements material to the Motion for Summary Judgment.

The Motion for Summary Judgment has been fully briefed according to the parties' agreed briefing schedule, which was proposed by the PSC and entered by Judge Saylor. Accordingly, the Tennessee Clinic Defendants' respectfully request that the Court:

- (1) Deny the PSC's Motion for Leave to File a Reply,
- (2) Disregard the proposed sur-reply, and
- (3) Decide the Tennessee Clinic Defendants' Motion for Summary Judgment.

care when performing the procedures. It requests a ruling solely on the issue of whether the Plaintiffs were required to file a certificate of good faith with their original complaints.

²⁷ The primary issue before the Court in the Motion for Summary Judgment is whether the Plaintiffs were required to file a certificate of good faith with their original complaints as required by Tenn. Code Ann. § 29-26-122. The Plaintiffs contend they were not required to file the required certificate with complaints alleging only claims styled as product liability claims, as opposed to claims under Tennessee's Health Care Liability Act, which includes Tenn. Code Ann. § 29-26-122. TENN. CODE ANN. § 29-26-101, *et seq.* The Defendants argue that all of the Plaintiffs' claims, including those styled as "product liability" claims are "health care liability actions" that require the filing of a certificate of good faith because all of the claims fit the statutory definition of "health care liability action:"

"[A]ny civil action...alleging that a health care provider or providers have caused an injury related to the provision of...health care services to a person, regardless of the theory of liability on which the action is based."

TENN. CODE ANN. § 29-26-101(a)(1).

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the CM/ECF system will be served electronically to the registered participants identified on the Notice of Electronic Filing and copies will be e-mailed or mailed via regular U.S. mail to those participants identified as unregistered this 9th day of April, 2014.

/s/ Chris J. Tardio

Chris J. Tardio

²⁸ Admitted pursuant to MDL Order No. 1.

²⁹ Admitted *pro hac vice*.